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Accuracy of the ElastPQ® Technique for the Assessment of Liver Fibrosis in Patients with Chronic Hepatitis C: a "Real Life" Single Center Study

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ABSTRACT

Background & Aims: Noninvasive assessment of liver stiffness has been increasingly used to evaluate fibrosis instead of liver biopsy, especially in patients with chronic viral hepatitis. The aim of this study was to assess the performance in staging liver fibrosis of the updated ElastPQ® technique (EPIQ7 ultrasound system, Philips Healthcare, Bothell, WA, USA) in the "real life" setting by using the FibroScan as the reference standard and to understand whether the use of the quality criteria improves the performance of the technique.
Methods: This was a cross-sectional study: 278 patients affected by chronic hepatitis C referred for liver stiffness measurement with the FibroScan® 502 Touch device (Echosens, Paris, France) underwent measurements also with the ElastPQ® technique. For the assessment of significant fibrosis (F≥2), advanced fibrosis (F≥3) and cirrhosis (F=4), respectively, we used the cutoffs of 7.0, 9.5 and 12.0 kPa. The diagnostic performance of ElastPQ® was assessed using the area under the ROC (AUROC) curve analysis and was evaluated overall and for cases with (a) 10 measurements and IQR/M≤30%, (b) 5 measurements and IQR/M ≤30%, (c) 10 measurements and IQR/M>30%, (d) 5 measurements and IQR/M>30%.
Results: The optimal cutoffs of ElastPQ® for significant fibrosis, advanced fibrosis and cirrhosis were 6.43, 9.54 and 11.34 kPa, respectively. For measurements with an IQR/M≤30%, there was no statistically significant decrease in sensitivity between 10 and 5 measurements (p=0.26, p=0.09, p=0.71, for F≥2, F≥3, and F=4, respectively).
Conclusion: The ElastPQ® technique is reliable and accurate for staging liver fibrosis. The number of measurements does not affect the performance.

Key words: transient elastography – shear wave elastography – liver cirrhosis – chronic hepatitis C – liver stiffness.

Abbreviations: ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase; AUROC: area under the ROC curve; BMI: body mass index; GGT: gamma-glutamyl transferase; LR: likelihood ratio; LSM: liver stiffness measurement; pSWE: point shear wave elastography; ROC: receiver operating characteristic; VCTE: vibration controlled transient elastography; VTQ®: virtual touch quantification.

INTRODUCTION

Noninvasive assessment of liver stiffness by means of shear wave elastography techniques has been increasingly used to evaluate fibrosis instead of liver biopsy, especially in patients with chronic viral hepatitis.

The recent availability of direct-acting antivirals for the eradication of the hepatitis C virus has prompted the European Association for the Study of the Liver (EASL) together with the Asociación Latinoamericana para el Estudio del Hígado (ALEH) to produce guidelines for the clinical use of non-invasive tests for evaluation of liver disease severity and prognosis [1].

Besides vibration controlled transient elastography (VCTE), which is available only on the FibroScan 502 Touch device and is the most validated technique for the assessment of liver stiffness, shear wave elastography techniques are implemented in conventional ultrasound systems, thus allowing the morphological evaluation of the liver in B-mode also. In a limited resource world this advantage is particularly important.

ElastPQ® is a point shear wave elastography (pSWE) technique implemented in the ultrasound systems of the

Philips Healthcare (Bothell, WA, USA). We have previously showed that, by using liver biopsy as the reference standard, the performance for the staging of liver fibrosis of the ElastPQ® technique which was implemented in the iU22 system was similar to that of VCTE [2]. Over the years, an updated ElastPQ® software has been released and is currently available. Recently, the consensus conference of the Society of Radiologists in Ultrasound has recommended that the report for US-based elastography should provide the median value of 10 measurements of liver stiffness, as well as the interquartile range/median (IQR/M) value as a measure of quality [3]. To the best of our knowledge, no study has been published which has proven a better performance of the ElastPQ® technique when these criteria are fulfilled.

The aim of this study was to assess the performance in the staging of liver fibrosis of the updated ElastPQ® technique in "real life" by using VCTE as the reference standard and to understand whether the use of the quality criteria improves the accuracy of the technique for staging liver fibrosis in patients with chronic hepatitis C.

MATERIAL AND METHODS

This was a single center cross-sectional study. Between February 2015 and January 2016 all consecutive patients affected by chronic hepatitis C referred to the ultrasound unit of the infectious diseases department of our institution for liver stiffness measurement (LSM) with the FibroScan 502 Touch® device, who voluntarily accepted to undergo LSM also with the ElastPQ® technique, were prospectively enrolled. Patients were asked to fast for at least six hours before the assessment of liver stiffness. Subject characteristics and biochemical tests, when available, were recorded. Diagnosis of chronic hepatitis C was based on the presence of detectable HCV-RNA and of elevated (at least transiently) serum alanine aminotransferase level.

Point shear wave elastography with the ElastPQ® technology

The examinations were performed by using the EPIQ7 ultrasound system (Philips Healthcare, Bothell, WA, USA) with a convex broadband probe and the ElastPQ® technique. This system has an updated ElastPQ® software with respect to the previous iU22 system. Measurements were performed in the right lobe of the liver through intercostal spaces following the recommended procedure [4]. Three physicians independently performed the pSWE measurements before the assessment with VCTE. Measurements were performed while patients were holding their breath for a few seconds during a steady breathing [3]. We previously assessed the interobserver variability in the ElastPQ® measurements and reported a concordance correlation coefficient of 0.93 (95%CI: 0.90-0.95) [2]. Each single ElastPQ® measurement is the mean value obtained with a sequence of several push-pulses; the mean value as well as the standard deviation are displayed on the screen of the system. We arbitrarily rejected the measurement when the standard deviation was higher than 30% of the absolute value. For each patient, the measurements of liver stiffness were consecutively obtained in the same location. An attempt was made to collect 10 valid measurements in each patient and to use the median value of these measurements, expressed in kiloPascal (kPa), and the IQR/M ratio for statistical analysis. Only the median (M) values that were obtained with at least 5 measurements were used for the analysis. We considered unreliable all cases with less than 5 measurements; LSMs were considered failures when no value was obtained after 10 attempts.

Vibration controlled transient elastography (VCTE)

VCTE was carried out by using the FibroScan 502 Touch® device (Echosens, Paris, France). The physician performing all the examinations had experience of at least 500 VCTE procedures. Measurements of liver stiffness were performed following the examination procedure previously described [5]. Examinations were performed with the M+ probe when the skin-to-liver capsule distance was ≤ 25 mm, otherwise the XL probe was used.

As reported in the literature, only LSM with 10 validated measurements and an IQR/M <30% for values higher than 7.1 kiloPascal (kPa) were considered reliable [6].

For the assessment of significant fibrosis (F ≥ 2), advanced fibrosis (F ≥ 3) and cirrhosis (F = 4), respectively, we used the cutoffs reported in a recent meta-analysis, i.e. 7.0, 9.5, and 12.0 kPa [7].

The study protocol was approved by the institutional Ethics Committee and was in accordance with the Helsinki Declaration of 1975, as revised in 2008. Informed written consent was obtained from all subjects before being included in the study.

Statistical analysis

Power considerations: considering a prevalence of fibrosis of about 50%, enrolling about 280 patients, 140 will be diseased. Considering a sensitivity of about 80%, a sample size of 140 produces a two-sided 95% confidence interval with a width equal to 9%.

Descriptive statistics were produced for demographic characteristics for this study sample of patients. The Shapiro-Wilk test was used to test the normal distribution of quantitative variables. When quantitative variables were normally distributed, the results were expressed as the mean value and standard deviation (SD), otherwise median and interquartile range (IQR; 25th -75th percentile) were reported. Qualitative variables were summarized as counts and percentages.

The diagnostic performance of ElastPQ® for staging liver fibrosis compared to VCTE (reference standard) was assessed using receiver operating characteristic (ROC) curves and the area under the ROC (AUROC) curve analysis. Associated with any cut off value is the probability of a true positive (sensitivity) and the probability of a true negative (specificity). The best discriminant cutoff level for each stage of liver fibrosis with a positive predictive value (PPV) of at least 90% was chosen. To assess whether the use of quality criteria improves the diagnostic accuracy, the performance of ElastPQ® was evaluated overall and for the cases with (a) 10 valid measurements and a ratio IQR/M ≤ 30% , (b) 5 valid measurements and a ratio IQR/M ≤ 30%, (c) 10 valid measurements and a ratio IQR/M > 30%, (d) 5 valid measurements and a ratio IQR/M > 30%.

P<0.05 was considered statistically significant. All tests were two-sided. The data analysis was performed with the STATA

statistical package (release 14.0, 2015, Stata Corporation, College Station, Texas, USA).

RESULTS

Two hundred and seventy-eight patients (161 males and 117 females) were studied. The main clinical and demographic characteristics of the study cohort are reported in Table I. The XL probe was used in 14 (5.0%) patients due to skin-to-liver capsule distance >25 mm.

Failures of LSMs were observed in 8 (2.9%) patients with ElastPQ® and 1 (0.4%) with VCTE. They were due to obesity in 7 patients and to narrow intercostal spaces in 1 patient in whom LSM failed with both techniques. Unreliable results were observed in 14 (5.0%) patients with ElastPQ® and none with VCTE. The unreliable results with ElastPQ® were due to obesity in 4 cases, to narrow intercostal spaces in 4 cases and to poor patient's compliance in the remaining 6 cases. Measurements performed with both ElastPQ® and VCTE were available for 255/278 (91.7%) patients.

Ten measurements were obtained in 243/255 (95.3%) patients, 147/243 (60.5%) of whom showed an IQR/M ≤ 30% and 96/243 (39.5%) an IQR/M > 30%. Five measurements were obtained in 255/255 (100%) patients, 193/255 (75.7%) of whom showed an IQR/M ≤ 30% and 62/255 (24.3%) an IQR/M >30%.

The overall median values of liver stiffness for each fibrosis stage of ElastPQ® and VCTE are reported in Table II. The sample size for the assessment of the diagnostic performance of ElastPQ® overall and for each category, i.e. IQR/M and number of measurements, is reported in Table III. The optimal thresholds for significant fibrosis (F ≥ 2), advanced fibrosis (F ≥ 3) and liver cirrhosis (F=4) with a positive predictive value > 90% were 6.43, 9.54, and 11.34 kPa, respectively. Figure 1 reports the diagnostic performance of the ElastPQ® technique. For measurements with an IQR/M ≤30%, there was not any statistically significant decrease in sensitivity between 10 and 5 measurements: 90.8% (81.9 - 96.2) and 86.5% (78.4 - 92.4), p=0.26; 90.0% (78.2 - 96.7) and 83.3% (72.7 - 91.1), p=0.09; 68.9% (53.4 - 81.8) and 66.7% (53.7 - 78.0), p=0.71; for F ≥ 2, F ≥ 3, and F = 4, respectively.

Table I. Patient demographics and biochemical tests

Characteristics	n =278
Sex, men (%)	161 (57.9%)
Age, years (SD)	59.3 (14.4)
BMI, kg/m^2 (SD)	24.4 (4.2)
AST, IU/L (IQR)	35 (23-60)
ALT, IU/L (IQR)	41 (22-70)
GGT, IU/L (IQR)	38 (23-79)
ALP, IU/L (SD)	75.6 (28.8)
Platelet count, 10^3/mm^3 (SD)	175.3 (69.6)
Fibrosis stage (as assessed with VCTE)	
Mild/no fibrosis (F0-F1)	127 (45.8%)
Significant fibrosis (F2)	45 (16.3%)
Advanced fibrosis (F3)	21 (7.6%)
Liver cirrhosis (F4)	84 (30.3%)

SD: standard deviation; IQR: interquartile range; BMI: body mass index; AST: aspartate aminotransferase; ALT: alanine aminotransferase; GGT: gamma-glutamyl transferase; ALP: alkaline phosphatase; VCTE: vibration controlled transient elastography.

Table II. Median values of liver stiffness for each fibrosis stage of the point shear wave elastography method and the vibration controlled transient elastography method.

Fibrosis stage	pSWE, kPa	VCTE, kPa
Mild/no fibrosis (F0-F1)	4.6 (4.1 – 5.5)	5.4 (4.4 – 6.1)
Significant fibrosis (F2)	7.3 (5.5 – 8.7)	8.1 (7.7 – 8.7)
Advanced fibrosis (F3)	8.9 (7.4 – 11.0)	10.4 (10 – 11.3)
Liver cirrhosis (F4)	13.3 (10.4 – 18.2)	20 (15.4 – 28.8)

pSWE: point shear wave elastography; VCTE: vibration controlled transient elastography; kPa: kiloPascal.

DISCUSSION

Shear wave elastography techniques are available in several ultrasound equipments and permit the estimation of liver stiffness non-invasively. Following the procedure suggested in the past for the assessment of liver stiffness with the FibroScan®

Table III. Sample size for the performance of the point shear wave elastography method.

	Significant fibrosis (F ≥ 2)	Advanced fibrosis (F ≥ 3)	Liver cirrhosis (F = 4)
Overall (n=255)	*n=133 (52.2%)	$^{+}$n=95 (37.2%)	§n=80 (31.4%)
	^n=112 (47.8%)	$^{\#}$n=160 (62.7%)	°n=175 (68.6%)
IQR/M≤30% and 10 measurements (n=147)	*n= 76 (51.7%)	$^{+}$n=50 (34.0%)	§n= 45 (30.6%)
	^n= 71 (48.3%)	$^{\#}$n=97 (66.0%)	°n= 102 (69.4%)
IQR/M ≤30% and 5 measurements (n=193)	*n=104 (53.9%)	$^{+}$n=72 (37.3%)	§n= 63 (32.6%)
	^n= 89 (46.1%)	$^{\#}$n=121 (62.7%)	°n= 130 (67.4%)
IQR/M>30% and 10 measurements (n=96)	*n=52 (54.2%)	$^{+}$n=40 (41.7%)	§n=31 (32.3%)
	^n=44 (45.8%)	$^{\#}$n=56 (58.3%)	°n=65 (67.7%)
IQR/M>30% and 5 measurements (n=62)	*n=29 (46.8%)	$^{+}$n=23 (37.1%)	§n= 17 (27.4%)
	^n=33 (53.2%)	$^{\#}$n=39 (62.9%)	°n= 45 (72.6%)

*positive group: F2, F3, F4; ^negative group: F0, F1; $^{+}$positive group: F3, F4; $^{\#}$negative group: F0, F1, F2; §positive group: F4; °negative group: F0, F1, F2, F3

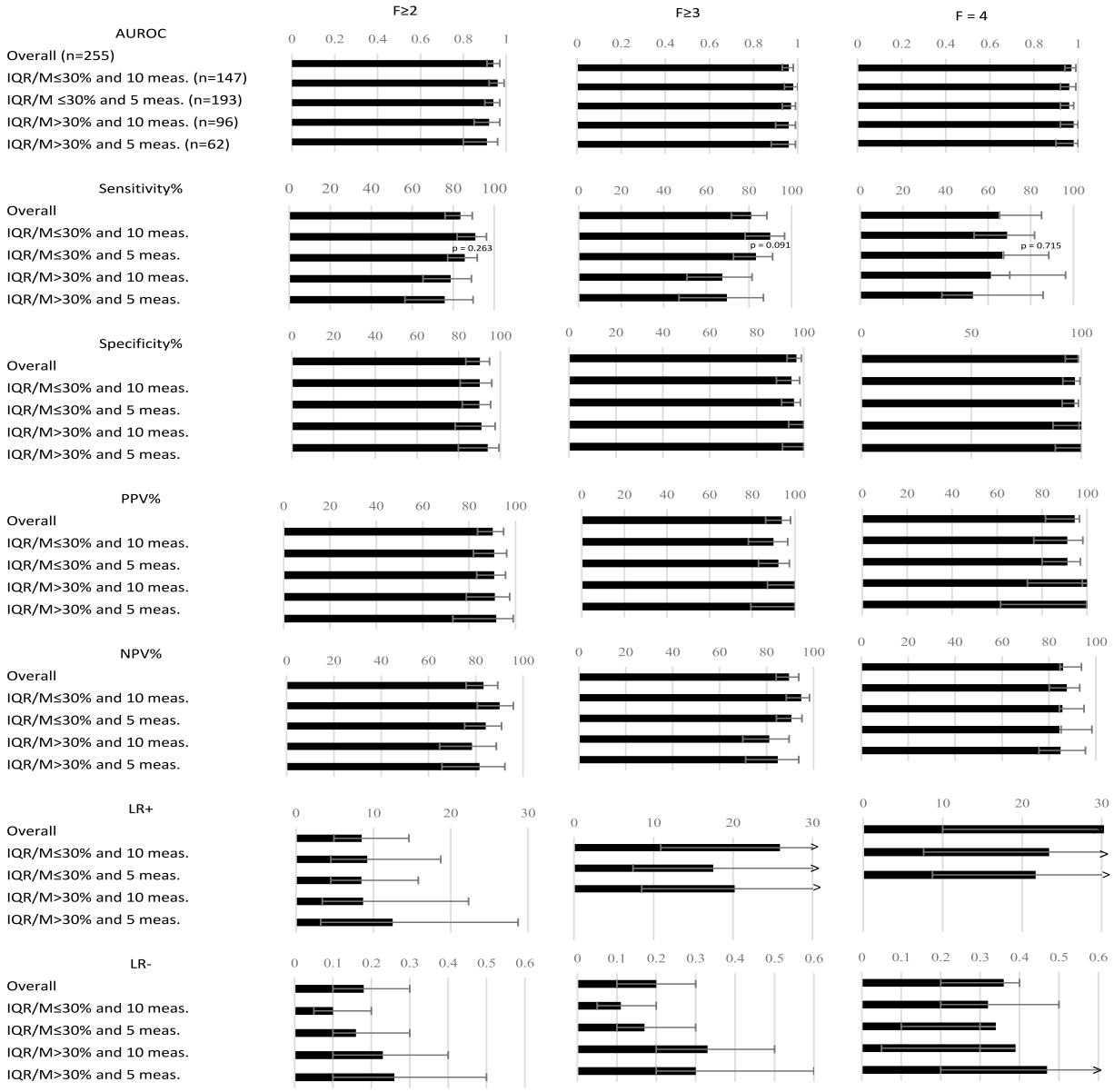

Fig. 1. The diagnostic performance of the ElastPQ® technique. Each bar represents the value with the 95% confidence interval. AUROC: area under the receiver operating characteristic curve; IQR: interquartile range; M: median; PPV: positive predictive value; NPV: negative predictive value; LR+: positive likelihood ratio; LR-: negative likelihood ratio.

device, it has been recommended that 10 measurements with an IQR/M ≤ 30% should be regarded as a quality factor [3, 8]. However, the total number of measurements required to obtain an accurate estimate of liver stiffness was not defined in research studies in large series of patients. The results of our study show that the accuracy of the ElastPQ® in the staging of liver fibrosis technique is not affected by the number of measurements. Moreover, it was possible to obtain an assessment of liver stiffness in a higher proportion of subjects without a decrease in accuracy. In our "real life" series, 10 measurements with an IQR/M ≤ 30% were obtained in 147/255 (57.6%) patients. Thus, in almost one case out of two, the LSMs would have been considered not reliable. Based on the results of our study, we believe that 5 consecutive measurements with an IQR/M ≤ 30% could be adequate for a reliable estimate of liver stiffness in the everyday clinical setting when there is a poor patient compliance or it is not possible to collect 10 valid measurements. In our study, the most important quality criterion was IQR/M ≤ 30%. Indeed, only when this criterion was not fulfilled, the sensitivity of the method significantly decreased. On the other hand, by using VCTE and liver biopsy as the reference standard, it has been shown that the number of measurements or the success rate had no significant influence on the staging of liver fibrosis [6, 9, 10]. In particular, Kettaneh et al. compared the AUROCs for the prediction of cirrhosis between the median values of the 3 first, the 5 first and the 10 first successful shots of VCTE and reported that there was no significant loss in performance if only 5 valid shots were obtained [10]. Using the VTQ®technique, which is the point shear wave elastography method implemented in the Siemens systems, Bota et al. reported that the correlation with fibrosis was r=0.722 when the quality parameters for measurements were fulfilled (IQR <30% and success rate ≥ 60%), whereas for IQR ≥30% and success rate < 60% the correlation dropped to r=0.268 [11].

With respect to other studies, we observed a very low rate of failures with VCTE [12, 13]. This difference may be due to the use of the XL probe when the skin-to-liver capsule distance was greater than 25 mm. The higher rate of failures reported by others could be due to the fact that these studies were performed before the availability of the XL probe, thus only the M probe, which is not appropriate for obese patients, was used. ElastPQ® measurements failed in 8/278 (2.9%) patients and were unreliable in 14/278 (5.0%) patients. The failures or unreliable results were mainly due to obesity. We hypothesize that, in these cases, the thickness of the subcutaneous tissue might decrease the strength of the push pulse of the ultrasound beam, which results in a poor signal-to-noise ratio displacement. We used VCTE as the reference standard. It could be a limitation of the study. However, nowadays the non-invasive assessment of liver fibrosis has been accepted as a reliable substitute of liver biopsy which, beside being an invasive procedure, is not the perfect gold standard since it has several limitations, including the intra- and inter-observer variability in the staging of liver fibrosis. The VCTE was the first non-invasive method available for the assessment of liver stiffness, and it is the most validated one. On the other hand, with the availability of the highly effective novel antiviral agents for HCV infected patients, the most important endpoint is the detection of cirrhosis, which establishes the necessity of treatment [1]. In our series, to maximize the probability of disease among patients with a positive test, we chose the optimal cut-offs with a PPV greater than 90% for the diagnosis of significant fibrosis, advanced fibrosis and liver cirrhosis.

CONCLUSION

The results of this study show that the updated version of the ElastPQ® technique is reliable and accurate for staging liver fibrosis. The number of measurements did not affect the technique performance, instead the criterion of IQR/M ≤ 30% should always be fulfilled.

Conflicts of interest: G. Ferraioli has served as a speaker for Philips Medical Systems, Hitachi Ltd, Toshiba Medical Systems. C. Filice has served as a speaker for Philips Medical Systems, Hitachi Ltd, and has received research funding from Bracco Imaging, Hitachi-Aloka Medical Systems, Toshiba Medical Systems. The other authors have no conflict of interest to declare.

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Author contributions: F.G. and T.C. designed the research. F.G., M.L. and L.R. performed the examinations, the literature search and article selection. T.C. and De S.A. performed the statistical analysis: F.G. wrote the article; M.L., L.R., T.C., De S.A. and F.C. reviewed the manuscript. All these authors and the Liver Fibrosis Study Group approved the final version.

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Acuratețea tehnicii ElastPQ® pentru evaluarea fibrozei hepatice la pacienții cu hepatită cronică virală C: studiu din practica în viața reală a unui singur centru

ABSTRACT / REZUMAT

Premize și scop: Evaluarea noninvazivă a rigidității hepatice este tot mai frecvent utilizată pentru aprecierea fibrozei în locul biopsiei hepatice, mai ales la pacienții cu hepatită cronică virală. Scopul acestui studiu a fost de a evalua performanța tehnicii ElastPQ® (system ecografic EPIQ7, Philips Healthcare, Bothell, WA, USA) pentru stadializarea în practică a fibrozei hepatice, utilizând FibroScan-ul ca referință standard, și de a stabili dacă utilizarea criteriilor de calitate ameliorează performanța tehnicii.

Metodă: Într-un studiu cros-secțional, 278 pacienți cu hepatită cronică C trimiși pentru măsurarea rigidității hepatice cu echipamentul FibroScan® 502 Touch (Echosens, Paris, France) au fost investigați și prin tehnica ElastPQ®. Pentru stabilirea fibrozei semnificative (F≥2), a fibrozei avansate (F≥3) și a cirozei (F=4), am utilizat valorile cutoff (de delimitare) de 7.0, 9.5, respectiv 12.0 kPa. Performanța diagnostică a ElastPQ® a fost stabilită prin analiza ariei de sub curba ROC (AUROC) și a fost evaluată global, și separat pentru cazurile cu (a) 10 măsurători și IQR/M≤30%, (b) 5 măsurători și IQR/M ≤30%, (c) 10 măsurători și IQR/M>30%, și (d) 5 măsurători valide și IQR/M>30%.

Results: Valorile cutoff optime obținute prin ElastPQ® pentru fibroza semnificativă, avansată și ciroză au fost de 6.43, 9.54, respectiv 11.34 kPa. Pentru măsurătorile cu IQR/M≤30%, nu a existat o reducere semnificativă statistic a sensibilității între 10 și 5 măsurători (p=0.26, p=0.09, p=0.71, pentru F≥2, F≥3 și, respectiv, F=4).

Concluzie: Tehnica ElastPQ® este o metodă corectă și precisă de stadializare a fibrozei hepatice. Numărul de măsurători efectuate nu influențează performanța sa.